JUN 2 9 2011 K103495

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SECTION 3 → 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Date: June 17, 2011

807.92(a)(2)

Trade Name: **ASICO SofTip Injector System, AS-9300**

Common Name: Injector

Classification Name(s): Intraocular lens guide,

Classification Number: CFR 886.4300
Regulatory class : Class I (Reserve)

807.92(a)(3)

Predicate Device(s)

	Device
K040837	MULTIJECT INJECTOR AND MICROGLIDE CARTRIDGE
K092023	NAVIJECT SUB2-1P, MODEL: LP604430
K063802	LENSTEC LC INJECTION SYSTEM

807.92 (a)(4)

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Device Description

The ASICO SofTip Injector system is a sterile, single use device intended to insert a foldable intraocular lens through a surgical procedure in a Human eye. The system provides a tubular pathway through a incision, allowing the delivery of a IOL into the Human eye. This is indicated for the insertion only of models of intraocular lens that allow use of this injector in their approved labelling

The plunger's head is covered by a silicone cushion that provide a good contact to the lens to ensure a smooth delivery. The plunger is advanced by direct forward motion applied to the syringe type plunger. The set consists of a disposable injector, a cartridge and a silicone tip.

There are different Injector sets based on the type of cartridge that is used (AS-9300-16, AS-93001620, AS-9300-24,AS-9300-2420)

The product is manufactured according to the ISO 13485:2003 Quality Standards and Quality System Regulations.

The Injector body is manufactured from Polycarbonate 144R Blue. The plunger assembly which consists of plunger, shaft and outer and inner cap is made up of, Polycarbonate 144R white and the spring is made of stainless steel (SS304) under validated conditions. The cartridge is made from medical grade lubricated polypropylene and the silicon tip is also from medical grade.

The injector system will be delivered sterile.

807.92(a)(5)

Technological Characteristics

The ASICO SofTip Injector system is a sterile, single use device intended to insert a foldable intraocular lens through a surgical procedure in a Human eye. The system provides a tubular pathway through a incision , allowing the delivery of a IOL into the Human eye. The plunger's head is covered by a silicone cushion that provide a good contact to the lens to ensure a smooth delivery. The plunger is advanced by direct forward motion applied to the syringe type plunger. This instrument has substantially equivalent technological characteristics to the predicate devices refer to the device matrix comparison chart below. The set consists of a disposable injector, a cartridge and a silicone tip.

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Device Comparison Matrix

TRADE NAME	ASICO AS Injector system; AS-9300	I MULTIJECT INJECTOR AND MICROGLIDE CARTRIDGE **K040837**	NAVIJECT SUB2-1P; MODEL LP604430 **K092023**	LENSTEC LC INJECTION SYSTEM **K063802**
Manufacturer	ASICO LLC	MEDICEL AG	MEDICEL AG	Lenstec LC
Regulation number	886.4300	886.4300	886.4300	886.4300
Product Code	MSS	MSS	MSS	MSS
Device Description	Intraocular Lens Guide	Intraocular Lens Guide	Intraocular Lens Guide	Intraocular Lens Guide
510(k) Number	Via this submission	K040837	K092023	K063802
Operating principle	The cartridge is loaded into the Injection System and the IOL is pushed through the cartridge into the eye	The cartridge is loaded into the Injection System and the IOL is pushed through the cartridge into the eye	The cartridge is loaded into the Injection System and the IOL is pushed through the cartridge into the eye	The cartridge is loaded into the Injection System and the IOL is pushed through the cartridge into the eye
Patient Contact	Tip of the Injector to place the lens	Tip of the Injector to place the lens	Tip of the Injector to place the lens	Tip of the Injector to place the lens
Intended Use	The ASICO SofTip Injector system is a sterile, single use device intended to insert a foldable intraocular lens through a surgical procedure in a Human eye. The system provides a tubular pathway through a incision , allowing the delivery of a IOL into the Human eye. This is indicated for the insertion only of models of intraocular lens that allow use of this injector in their approved labelling	The Medicel MultiJect injector for the intraocular lenses is indicated for the insertion of foldable intraocular lenses Ceeon913A and Tecnis Z9000 made by Pharmacia when used in conjunction with the Micro Glide cartridges	The Navijet Sub2-1P IOL injector and cartridge set for the intraocular lens is indicated for the insertion only of models of intraocular lens that allow use of this injector in their approved labelling	The Lenstec LC Injection system is intended for use in implantation of Staar Collamer Intraocular Lens model CC4204BF into the capsular bag following extracapsular extraction

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DE NAME	ASICO AS Injector system, AS-9300	I MULTIJECT INJECTOR AND MICROGLIDE CARTRIDGE **K040837**	NAVIJECT SUB2-1P, MODEL: LP604430 **K092023**	LENSTEC LC INJECTION SYSTEM **K063802**
Materials	1.Outer Body - Polycarbonate 144R BLUE 2.Plunger - Polycarbonate 144R WHITE 3.Cap - Polycarbonate 144R WHITE 4. spring is made of SS304	Unable to Obtain	Unable to Obtain	1.Outer Body - Polycarbonate 144R BLUE 2.Plunger - Polycarbonate 144R WHITE 3.Cap - Polycarbonate 144R WHITE 4. spring is made of SS304
Forward motion principle	Plunger/Syringe/screw Type	Plunger/Syringe Type	Plunger/Syringe Type	Plunger/Syringe Type
Design	is a sterile, single use device	is a sterile, single use device	is a sterile, single use device	is a sterile, single use device
Sterilization	Single use device	Single use device	Single use device	Single use device
Where used	Hospital/ surgery centre	Hospital/ surgery centre	Hospital/ surgery centre	Hospital/ surgery centre
ompatible	Yes	Yes	Yes	Yes
Recommend to use with	FDA approved viscoelastic	FDA approved viscoelastic	FDA approved viscoelastic	FDA approved viscoelastic
Sterilization Method	ETO sterilization SAL Level $1X10^{-6}$	ETO sterilization Unable to Obtain SAL level	ETO sterilization Unable to Obtain SAL level	ETO sterilization SAL Level $1X10^{-6}$
Diameter of Barrel Tip	5mm	Unable to Obtain	Unable to Obtain	5mm
Human Factors	By Doctors only	By Doctors only	By Doctors only	By Doctors only
Standards Met	ISO 11979-3: 2006 ISO 10993-5:2009 ISO 10993-10:2002 ISO 10993-10:2002	Unable to Obtain	Unable to Obtain	ISO 11979-3: 2006 ISO 10993-5:2009 ISO 10993-10:2002 ISO 10993-10:2002
Performance	Performance criteria met	Performance criteria met	Performance criteria met	Performance criteria met

Most of the predicate devices use the same principal (plunger/syringe type) to implant the lens into the eye and there for is very similar to each other. Difference can be the composition of the instrument. All the devices including ASICO AS-9000 injection system have been tested to according to Recognized Consensus Standards ISO 11979-3:2006, Ophthalmic implants -- Intraocular lenses -- Part 3: Mechanical properties and test methods. (Ophthalmic): and they have passed the tests.

There is nothing in the ASICO AS9000 injection system that negatively affects the safety or performance o

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Tests Performed

The objective of the study was to demonstrate that the IOL's remain mechanically and optically undamaged after manipulation with the AS-9300 injection system. The instrument has passed all the necessary tests.

We have performed various bio compatibility tests. As per FDA guidelines we have done the following tests. Cytotoxicity Test, ISO Systematic Toxicity Test, Intracutaneous Test and Maximization Sensitization Test. Test results below.

Test	ISO Standard	Summary	Test Result
Cytotoxicity Test	ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	**The Test article extract showed no evidence of causing cell lysis or toxicity. The test article extract met the requirements of the test since the grade was less than grade 2(mild reactivity)**	**Passed**
ISO Systematic Toxicity Test	ISO 10993-11:2006 Biological evaluation of medical devices Part 11: Tests for systemic toxicity	**There was no mortality or evidence of systemic toxicity from the extracts. The test article extracts met the requirements of the study**	**Passed**
Intracutaneous Test	ISO 10993-10:2002 / And 1:2006 Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	**There was no Erythema and no edema from the SC test extract injected intracutaneously into the rabbits. There was very slight erythema and no edema from the SO test extract injected Intracutaneously into rabbits. Each test article met the requirements of the test since the difference between the test extract overall mean score and corresponding control overall mean score was 0.0**	**Passed**
Maximization Sensitization Test	ISO 10993-10:2002/Amd 1:2006 Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity	**The test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered sensitizers in the guinea pig maximization test.**	**Passed**

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We also have done a 5 year ageing study on the cartridge. The cartridges and silicone are being supplied to us by Lenstec which is one of our predicate companies. The plastic injector is supplied to Lenstec by us. We have included their report as it shows the IOL's remain mechanically and optically undamaged after manipulation. The Sterilization Validity study has been performed. .

Substantial Equivalence Discussion

The ASICO SofTip Injector system is a sterile, single use device intended to insert a foldable intraocular lens through a surgical procedure in a Human eye. The system provides a tubular pathway through a incision , allowing the delivery of a IOL into the Human eye. This is indicated for the insertion only of models of intraocular lens that allow use of this injector in their approved labelling

The plunger's head is covered by a silicone cushion that provides a good contact to the lens to ensure a smooth delivery. The plunger is advanced by direct forward motion applied to the syringe type plunger. The set consists of a disposable injector, a cartridge and a silicone tip.

This instrument has substantially equivalent technological characteristics to the predicate devices the Navijet and the multi-jet system from Medicel as well Lenstec LC Injection system. They use the same principal and have a similar silicon tip, injector and cartridge.

ASICO cartridges are equivalent to Lenstec cartridges LC16, LC1620, LC24, LC2420. Lenstec supplies to ASICO the same cartridges and silicon tips they use. They combine their cartridges with Injectors that ASICO supplies and sterilizes them similar to their LC injection system which is our predicate device and supplies to ASCIO under the ASICO SofTip Injector System, AS-9300 brand name. A brief device comparison is below. A detailed comparison matrix is listed below.

Device Comparison Matrix

TRADE NAME	ASICO AS Injector system, AS-9300	I MULTIJECT INJECTOR AND MICROGLIDE CARTRIDGE **K040837**	NAVIJECT SUB2-1P MODEL LP604430 **K092023**	LENSTEC LC INJECTION SYSTEM **K063802**
Manufacturer	ASICO LLC	MEDICEL AG	MEDICEL AG	Lenstech LC
Target Population	Different Lens companies	Different Lens companies	Different Lens companies	Use for their own lens
Sterilization Method	ETO sterilization	ETO sterilization	ETO sterilization	ETO sterilization
Device Description	Intraocular Lens Guide	Intraocular Lens Guide	Intraocular Lens Guide	Intraocular Lens Guide
Operating principle	The cartridge is loaded into the	The cartridge is loaded into	The cartridge is loaded into the	The cartridge is loaded into the Injection System and the

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	Injection System and the IOL is pushed through the cartridge into the eye	the Injection System and the IOL is pushed through the cartridge into the eye	Injection System and the IOL is pushed through the cartridge into the eye	IOL is pushed through the cartridge into the eye
Patient Contact	Tip of the Injector to place the lens	Tip of the Injector to place the lens	Tip of the Injector to place the lens	Tip of the Injector to place the lens
Intended Use	The ASICO SofTip Injector system is a sterile, single use device intended to insert a foldable intraocular lens through a surgical procedure in a Human eye. The system provides a tubular pathway through a incision , allowing the delivery of a IOL into the Human eye. This is indicated for the insertion only of models of intraocular lens that allow use of this injector in their approved labelling	The Medicel MultiJect injector for the intraocular lenses is indicated for the insertion of foldable intraocular lenses Ceeon913A and Tecnis Z9000 made by Pharmacia when used in conjunction with the MicroGlide cartridges	The Navijet Sub2-1P IOL injector and cartridge set for the intraocular lens is indicated for the insertion only of models of intraocular lens that allow use of this injector in their approved labelling	The Lenstec LC Injection system is intended for use in implantation of Staar Collamer Intraocular Lens model CC4204BF into the capsular bag following extracapsular extraction

TRADE NAME	ASICO AS-Injector system, AS-9300	I MULTIJECT INJECTOR AND MICROGLIDE CARTRIDGE	NAVIJECT SUB2-1P, MODEL LP604430 **K092023**	LENSTEC LC INJECTION SYSTEM **K063802**

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Forward motion principle	Plunger/Syringe Type	Plunger/Syringe Type	Plunger/Syringe Type	Plunger/Syringe Type
Biocompatible	Yes	Yes	Yes	Yes
Design	is a sterile, single use device	is a sterile, single use device	is a sterile, single use device	is a sterile, single use device
Sterilization	Single use device	Single use device	Single use device	Single use device
Where used	Hospital/ surgery centre	Hospital/ surgery centre	Hospital/ surgery centre	Hospital/ surgery centre
Materials	1.Outer Body Polycarbonate 144R BLUE 2.Plunger Polycarbonate 144R WHITE 3.Cap Polycarbonate 144R WHITE 4. spring is made of SS304	Unable to Obtain	Unable to Obtain	1.Outer Body - Polycarbonate 144R BLUE 2.Plunger - Polycarbonate 144R WHITE 3.Cap - Polycarbonate 144R WHITE 4. spring is made of SS304

Summary

The test have been done according to Recognized Consensus Standards ISO 11979-3:2006, Ophthalmic implants -- Intraocular lenses -- Part 3: Mechanical properties and test methods. (Ophthalmic): The cartridges are being supplied to us by Lenstec which is one of our predicate companies. We have included their report as it shows the IOL's remain mechanically and optically undamaged after manipulation. We also have included a 5 year ageing study on the cartridge and injector. The Sterilization Validity study and summary are also included for review

We have performed various bio compatibility tests. As per FDA guidelines we have done the following tests. Cytotoxicity Test, ISO Systematic Toxicity Test, Intracutaneous Test and Maximization Sensitization Test

We thereby conclude that ASICO AS-9300 SofTip Injecotion system is has substantially equivalent technological characteristics to the predicate devices the Navijet and the multi-jet system from Medicel as well Lenstec LC Injection system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ASICO LLC
c/o Mr. Casey Conry
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
Melville, NY 11747

JUN 29 2011

Re: K103495
Trade/Device Name: ASICO SofTip Injector System, AS-9300
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I (reserve)
Product Code: MSS
Dated: June 17, 2011
Received: June 21, 2011

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K103495**

Device Name: __ **ASICO SofTip Injection System**

Indications for Use:

The ASICO SofTip Injector system is a sterile, single use device intended to insert a foldable intraocular lens through a surgical procedure in a Human eye. The system provides a tubular pathway through a incision , allowing the delivery of a IOL into the Human eye. This is indicated for the insertion only of models of intraocular lens that allow use of this injector in their approved labelling

Prescription Use ___**X**____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K103495